

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

CENTOCOR ORTHO BIOTECH, INC.)
AND NEW YORK UNIVERSITY,)
Plaintiffs,) CIVIL ACTION NO. 2:07CV139
v.)
ABBOTT LABORATORIES, ABBOTT) JURY TRIAL DEMANDED
BIORESEARCH CENTER, INC., and)
ABBOTT BIOTECHNOLOGY LTD.)
Defendants.)

)

**DEFENDANTS' MEMORANDUM IN RESPONSE TO PLAINTIFFS' JUDICIAL
ESTOPPEL ARGUMENT**

On May 19, 2009, this Court granted a motion for summary judgment by Defendants Abbott Laboratories, Abbott Bioresearch Center Inc. and Abbott Biotechnology Ltd. (collectively “Abbott”) that the priority date for U.S. Patent No. 7,070,775 (“the ‘775 Patent ”) should be no earlier than February 1994. Abbott’s motion for summary judgment, which was based on the doctrine of acquiescence, (“Abbott’s Acquiescence Motion”), did not address the substance of the enablement requirement under 35 U.S.C. § 112. Abbott’s motion instead was addressed to the procedural consequences arising from the actions taken before the United States Patent and Trademark Office (“USPTO”) by Plaintiffs Centocor Ortho Biotech Inc. and New York University (collectively “Centocor”) during the prosecution of the patent applications leading to the ‘775 patent.

In Abbott’s Acquiescence Motion, Abbott argued that (1) the USPTO had rejected claims in Centocor’s 1992 and 1993 related patent applications, U.S. Patent App. No. 07/943,852 (the ““852 application”) and U.S. Patent App. No. 08/013,413 (the ““413 application”), based on the failure of the specification to enable human or humanized antibodies; (2) Centocor acquiesced to these rejections by adding new matter to its February 1994 related patent applications¹ in an attempt to address the enablement rejections; and (3) Centocor therefore could not rely on any of the applications in the patent family of the ‘775 patent that were filed before February 1994 to support its claims.

¹ The 1994 patent applications are U.S. Patent App. Nos. 08/192,093 (the ““093 application”), 08/192,861 (the ““861 application”), and 08/192,102 (the ““102 application”).

Abbott did not argue in its motion—and the Court did not rule—that the earlier applications were not in fact enabling.² The merits of the enablement issues relating to Centocor's applications were not a subject of Abbott's motion.

Given the scope of Abbott's motion and the Court's ruling, there is no basis for estopping Abbott from arguing, in the alternative, that *if* the 1994 application enables human antibodies, *then* Centocor's previously published PCT application, WO 92/16553 (the "Le 1992 application"), which is materially identical to Centocor's 1992 patent applications,³ anticipates the asserted claims of the '775 patent because the new matter added in 1994 did not, in fact, cure Centocor's failure to enable human antibodies. Abbott's technical expert Dr. James Marks, unlike Centocor's expert Dr. Gregory Adams, expressly considered the 1994 material and explained that it was not enabling. Expert Report of Dr. James Marks at ¶ 239-240, ¶ 251, ¶ 242-249 (March 20, 2009) ("Marks Invalidity Report")

This alternative is expressly explained and opined upon in Dr. Marks expert report on invalidity. In paragraph 184, Dr. Marks provided the following opinion:

184. Neither the **Le 1992** nor **Knight 1993** reference discloses a working example of a humanized or human antibody. Accordingly, neither reference discloses an actual antibody that competitively inhibits A2 where the antibody has a "human" variable region, a "human" light chain, or a "human" heavy chain. **For the reasons stated below, the claims that are limited to antibodies having a human variable region (claim 2, 3, 14 and 15 of the '775 patent) are neither enabled nor adequately described. However, were the conclusion to be**

² Acquiescence addresses the issue of whether a patentee is entitled to a particular filing date. It does not address whether a patent application actually meets the enablement requirement of 35 U.S.C. § 112. *See Pennwalt Corp. v. Akzona Inc.*, 740 F.2d 1573, 1580 n. 13 (Fed. Cir. 1984).

³ Centocor has expressly admitted that "(1) an international patent application (WO 92/16553 ("Le 1992")) (Ex. 3) was filed by Centocor on March 18, 1992; (2) that application is materially identical to the 852 application; and (3) the 606 application is substantially identical to the Le 1992 application and, thus, also the 852 application." Plaintiff's Opposition to Defendants' Motion for Summary Judgment of Invalidity Based On Failure To Comply With the Written Description Requirement (Motion No. 2), at 2 (May 4, 2009).

reached that such claims are enabled and described, then the nearly identical disclosures of the Le 1992 and Knight 1993 references would equally describe and enable antibodies having a human variable region, and claims 2, 3, 14 and 15 would be anticipated.

Marks Invalidity Report at ¶ 184 (March 20, 2009) (underlining and bold emphasis in paragraph 184 added).

If it was the law of the case⁴ that the '852 patent application filed by Centocor in 1992 did not enable the asserted claims, then this case would be effectively over and decided in Abbott's favor. Centocor's technical expert Dr. Gregory Adams did not provide any opinion about the enablement of the 1994 patent applications. His only opinions on enablement were directed to the disclosures of the '852 patent application and its predecessors (the disclosures which, of course, are also present in the 1994 applications). If it is the law of the case that the disclosures of the '852 patent application (and therefore the materially identical disclosures of the Le 1992 application) are not enabling, Centocor's expert has no opinion to give on enablement of the 1994 patent application.⁵

⁴ Judicial estoppel is normally a doctrine that binds a party in a second proceeding based on a ruling in a prior case. For judicial estoppel to apply, "(1) the party's position must be clearly inconsistent with its previous one, and (2) the previous court must have accepted the party's earlier position." *Hopkins v. Cornerstone Am.*, 545 F.3d 338, 347 (5th Cir. 2008). As noted, Abbott's position at trial is consistent with the position in its summary judgment motion of acquiescence. Moreover, the court did not determine that the earlier applications were not enabled.

If the Court's acquiescence ruling had addressed the substance of the enablement argument, the Court's ruling would constitute the law of the case and equally bind Abbott and Centocor. *Kiker v. Hefner*, 409 F.2d 1067, 1068 (5th Cir. 1969).

⁵ It is Centocor's burden to show that the Le 1992 application is not enabling. When an accused infringer asserts that a prior art patent anticipates specific patent claims, the infringer enjoys a presumption that the anticipating disclosure also enables the claimed invention. *Impax Laboratories, Inc. v. Aventis Pharmaceuticals, Inc.*, 545 F.3d 1312, 1316 (Fed Cir. 2008). It is the patentee's burden to overcome the presumption with persuasive evidence showing that the prior art does not enable the claimed invention. *Id.*, see also *Amgen Inc. v. Hoechst Marion Roussel, Inc.* 314 F.3d 1313 (assigning error to the district court for shifting the burden of proving the prior art reference's enablement of the claimed invention on the alleged infringer).

In sum, Abbott intends to ask its expert to render an alternative opinion, *consistent* with his expert report, where he assumes, *consistent* with Centocor's position,⁶ that the disclosure of the 1992 application (as it appears in the 1994 application) enables human antibodies. This Court's ruling on acquiescence does not act as an estoppel against this opinion.

Dated: June 22, 2009

By: /s/ David J. Beck

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⁶ Centocor and its expert Dr. Adams has repeatedly argued that the asserted claims are enabled by the '852 application filed in September 1992 and earlier applications. Rebuttal Expert Report of Dr. Gregory Adams ¶ 157; ¶ 180-191 (Apr. 6, 2009). As an example, Dr. Adams opined that:

"I have reviewed the March 1991, March 1992, and September 1992 applications and understand what is disclosed therein. In my opinion, each of the March 1991, March 1992, and September 1992 applications provide sufficient disclosure to allow those having ordinary skill in the art to make and use the full scope of the asserted claims."

Id. at ¶ 157.

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CERTIFICATE OF SERVICE

I hereby certify that counsel of record, who are deemed to have consented to electronic service in the above-referenced case, are being served this 22nd day of June, 2009 with a copy of the above-document via the court's CM/ECF System per Local Rule CV-5(a)(3).

/s/ Michael E. Richardson
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